MAY - 2 2000

510(k) SUMMARY

510(k) NUMBER: ~~PENDING~~ k000545

SUBMITTED BY: Applied Medical Resources Corporation
26051 Merit Circle, Unit # 104
Laguna Hills, California 92653
(949) 582-6120

CONTACT PERSON: Anil Bhalani
Director of Regulatory Affairs and Clinical Programs

DATE OF PREPARATION: February 16, 2000

NAME OF DEVICE: Sentry™ Expanding Introducer Sheath (EIS)

CLASSIFICATION NAME: Laparoscope, General & Plastic Surgery (21CFR 876.1500)

TRADE NAME: Sentry™ Expanding Introducer Sheath (EIS)

PREDICATE DEVICES: Innerdyne Step Trocar Expandable Port, "Step" Product Family.

INTENDED USE: The Sentry™ Expanding Introducer Sheath (EIS) is intended to provide dilating access for laparoscopic trocars and instruments into the peritoneal or thoracic cavities. The EIS is intended for use in conjunction with the Sentry™ Insufflation Needle and Applied Medical Trocar Cannulas.

DEVICE DESCRIPTION: The Sentry™ Expanding Introducer Sheath (EIS) is a sterile single use device, consisting of a polyurethane sheath with stainless steel reinforcing spines held together by a hub made from aluminum. The hub has a septum seal incorporated in it to help prevent loss of pneumoperitoneum due to leakage of gas from between the EIS and the insufflation needle or trocar cannula. In its undeployed state the polyurethane sheath with the stainless steel reinforcing spines is folded together by a teflon split sheath wrapped around it. The teflon shrink tube is designed to tear when a cannula assembly allowing the sheath to unfold to a larger working size. In its undeployed state the sheath is approximately 90mm in length by 3mm in diameter along its shaft. When deployed, the sheath will expand to accommodate standard Applied Medical non-threaded 100mm long cannulas in sizes 5mm to 12mm.

PERFORMANCE DATA SUMMARY: The performance and functional testing of the EIS included tests to verify the insertion force of the EIS/insufflation needle assembly, insertion force required to insert the Applied Medical Cannula into the EIS and Leak Testing to verify leakage through the EIS Assembly. The performance and functional testing demonstrated that the Sentry™ Expanding Introducer Sheath is substantially equivalent to the predicate device and it introduces no new safety and effectiveness issues when used as instructed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2000

Mr. Anil Bhalani
Director of Regulatory Affairs and Clinical Programs
Applied Medical Resources Corporation
26051 Merit Circle, Unit #104
Laguna Hills, California 92653

Re: K000545
Trade Name: Sentry™ Expanding Introducer Sheath (EIS)
Regulatory Class: II
Product Code: GCJ
Dated: February 16, 2000
Received: February 18, 2000

Dear Mr. Bhalani:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lechner for

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K000545

INDICATIONS FOR USE

Applied Medical Resources is providing this separate cover page for the Sentry™ Expanding Introducer Sheath (EIS) "Indications for Use" as required.

510(k) Number: ~~Not assigned~~ K000545

Device Name: Sentry™ Expanding Introducer Sheath (EIS)

Indications for Use: The Sentry™ Expanding Introducer Sheath (EIS) is intended to provide dilating access for laparoscopic trocars and instruments into the peritoneal or thoracic cavities. The EIS is intended for use in conjunction with the Sentry™ Insufflation Needle and Applied Medical Trocar Cannulas.

Signature: _____ Title: *Director RA/Clinical Programs* Date: *2-16-00*

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The -Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Donna R Lochner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000545